UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/537,285 | 06/01/2005 | Masahiro Ozaki | 272683US2XPCT | 1849 |

22850 7590 09/10/2007

OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

| EXAMINER | |
|---|---|
| FERNANDEZ, KATHERINE L | |
| ART UNIT | PAPER NUMBER |
| 3768 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 09/10/2007 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/537,285 | OZAKI ET AL. | |
| | Examiner | Art Unit | |
| | Katherine L. Fernandez | 3768 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *31 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 June 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/1/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

***Priority***

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

***Claim Objections***

2. Claims 3 and 23 are objected to because of the following informalities:

Claim 3 recites the limitation "second sick portion detecting device" in lines 5 and 7. There is insufficient antecedent basis for this limitation in the claim. The examiner assumes that claim 3 is dependent on claim 2, which does include the limitation "second sick portion detecting device".

Claim 23 recites the limitation "relating the position of the sick portion candidate detected at the sick portion detecting on the transformed image and displaying it" in lines 4-5. The examiner assumes that "at the sick portion detecting" is a typo, and limitation should read "relating the position of the sick portion candidate detected on the transformed image and displaying it".

Claim 28 recites the limitation "detecting a sick portion candidate based upon an image acquired bar a modality..." in line 2. Examiner assumes "bar" is a typo and should be corrected to "by".

Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 7, 14-15, 21, 23 and 26-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Gilhuijs et.al. (US Patent No. 6,317,617).

With regards to claim 1, Gilhuijs et al. disclose a computer aided diagnostic system, comprising: a sick portion detecting device (700) configured to detect a sick portion candidate based upon an image acquired by a first modality (i.e. MR imaging) (column 10, lines 3-41); and a correspondence displaying device (702) configured to relate the position of the detected sick portion candidate on an image acquired by a second modality (i.e. x-ray mammography, ultrasound) different from the first modality and to display it (column 14, lines 6-34).

With regards to claim 7, Gilhuijs et al. disclose a computer aided diagnostic system, comprising: a sick portion detecting device (700) configured to detect a sick portion candidate based upon an image acquired by one modality (i.e. MR imaging) (column 10, lines 3-41); an image transforming device configured to transform the image acquired by the modality (column 14, lines 6-25, referring to the MR data being segmented in such a way that it becomes suitable for visual and/or computerized comparison with images obtained from other modalities, and also the gray values being transformed so that they map to similar gray value regions and project the 3D image to the plane of mammograms); and a correspondence displaying device (702) configured to relate the position of the sick portion candidate detected by the sick portion detecting device on the transformed image and to display it (column 14, lines 6-34).

With regards to claims 14 and 26, Gilhuijs et al. disclose a computer aided diagnostic system and method, comprising: a sick portion detecting device configured to detect a sick portion candidate based upon an image acquired by a modality which can sense plural tomographic images (column 9, line 51-column 10, line 41; column 11, lines 60-67, referring to obtaining 3D data); an image reconfiguring device configured to reconfigure an image based upon stereoscopic image data acquired by the modality (column 11, lines 60-67, referring to using 3D data); and a corresponding displaying device (702) configured to relate the position of the sick portion candidate detected by the sick portion detecting device on the reconfigured image and to display it (column 14, lines 6-34). See Figure 2.

With regards to claims 15 and 27, Gilhuijs et al. disclose a computer aided diagnostic system and method, comprising: an image reconfiguring device configured to reconfigure an image based upon stereoscopic image data acquired by a modality which can sense plural tomographic images (column 9, line 51-column 10, line 41; column 11, lines 60-67, referring to obtaining 3D data); a sick portion detecting device configured to detect a sick portion candidate based upon the reconfigured image (column 9, line 51-column 10, line 41; column 10, line 47 through column 13, line 47, referring to detection process performed on 3D images); and a correspondence displaying device (702) configured to relate the position of the sick portion candidate by the sick portion detecting device on an image acquired by the modality to display it (column 14, lines 6-34). See Figure 2.

With regards to claim 21, Gilhuijs et al. disclose a computer aided diagnosing method, comprising: detecting a sick portion candidate based upon an image acquired by a first modality (i.e. MR imaging) (column 10, lines 3-41); and relating the position of the detected sick portion candidate on an image acquired by a second modality (i.e. X-ray mammogram, ultrasound) different from the first modality and displaying it (column 14, lines 6-34).

With regards to claim 23, Gilhuijs et al. disclose a computer aided diagnosing method, comprising: detecting a sick portion candidate based upon an image acquired by one modality (column 10, lines 3-41); transforming the image acquired by the modality (column 14, lines 6-25, referring to the MR data being segmented in such a way that it becomes suitable for visual and/or computerized comparison with images obtained from other modalities); and relating the position of the sick portion candidate detected on the transformed image and displaying it (column 14, lines 6-25, referring to gray values being transformed so that they map to similar gray value regions and project the 3D image to the plane of mammograms)

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 2-4, 6 and 8-11, 13, 16-18, 22, 24-25 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilhuijs et al. in view of Wang et al. (US Patent No. 7,103,205).

With regards to claims 2-4, 6, and 22, Gilhuijs et al. disclose a computer aided diagnostic system and method, comprising: a first sick portion detecting device configured to detect a sick portion candidate based upon an image acquired by a first modality (column 10, lines 3-41). They also disclose a correspondence displaying device (702) that would be capable of being configured to relate the position of a sick portion candidate detected by a first sick portion detecting device on an image analyzed by a second sick portion detecting device and displaying it at the same time (column 14, lines 6-34). The corresponding displaying device (702) would also be capable of being configured to display the following portion so that the portion can be identified in case the detection result synthesizing device judges that there is the portion detected as a sick portion candidate by only either of the first or second sick portion detecting device (column 14, lines 6-34). An image acquired by one modality is a simple X-ray radioscopic image (column 14, lines 6-9, lines 22-25).

However, they do not specifically disclose a second sick portion detecting device configured to detect a sick portion candidate based upon an image related to the same region of interest of the same subject acquired by a second modality different from the first modality and a detection result synthesizing device configured to compare the results of detection by the first and second sick portion detecting devices. Further, Gilhuijs et al. do not specifically disclose that an image acquired by either of the first or

second modality is an X-ray CT image. Wang et al. disclose an adjunctive ultrasound mammography system and method for interactive viewing of breast ultrasound information in a manner that complements x-ray mammogram viewing (column 3, lines 49-54). They disclose taking a first medical image (200) (i.e. x-ray mammography) with suspect region (202) identified, and also taking a second medical image (300) (i.e. ultrasound) with suspect region (302) identified (i.e. a sick portion candidate is detected based upon an image related to the same region of interest of the same subject acquired by a second modality different from the first modality) (column 8, lines 34-63). Further, they disclose that a bimodal medical image (400) is formed by the superposition of the medical images 200 and 300 (i.e. the results of the detection in the first and second medical images can be compared) (column 8, lines 44-55). Wang et al. also disclose that CT screening or MR screening can also be used in their invention (column 13, lines 25-46). See Figures 2-4. At the time of the invention, it would have been obvious to one of ordinary skill in the art to have included a second sick portion detecting device configured to detect a sick portion candidate and a detection result synthesizing device configured to compare the results of detection by the first and second sick portion detecting devices in the system of Gilhuijs et al, and further have an image acquired by either of the first or second modality be an X-ray CT image. The motivation for doing so would have been to recognize false positives and to provide further characterization of a suspect region, as taught by Wang et al. (column 8, lines 36-63).

With regards to claims 8, 13, and 24, Gilhuijs et al. disclose a computer aided diagnostic system and method comprising: an image transforming device (700) configured to transform an image acquired by one modality (column 14, lines 6-25, referring to the MR data being segmented in such a way that it becomes suitable for visual and/or computerized comparison with images obtained from other modalities, and also the gray values being transformed so that they map to similar gray value regions and project the 3D image to the plane of mammograms); and a correspondence displaying device (702) configured to relate the position of a sick portion candidate detected by a sick portion detecting device on the image acquired by the modality and to display it (column 14, lines 6-34). However, they do not specifically disclose a sick portion detecting device configured to detect a portion candidate based upon the transformed image. Further, Gilhuijs et al. do not specifically disclose that an image acquired by the modality is an X-ray CT image. As discussed previously, Wang et al. disclose that their invention includes creating a bimodal medical image (400) formed by the superposition of the medical images 200 and 300 (i.e. the results of the detection in the first and second medical images can be compared) (column 8, lines 44-55). Further, a suspect region 402 can be identified on the superimposed image (column 8, lines 52-55). Wang et al. also disclose that CT screening or MR screening can also be used in their invention (column 13, lines 25-46). See Figures 2-4. At the time of the invention, it would have been obvious to one of ordinary skill in the art to include in the invention of Gilhuijs et al. a sick portion detecting device configured to detect a portion candidate based upon the transformed image, and further have an image acquired by

the modality be an X-ray CT image. The motivation for doing so would have been that some features that may not be evident in either medical image may become apparent when the images are superimposed, as taught by Wang et al. (column 8, lines 52-55).

With regards to claims 9-11 and 25, Gilhuijs et al. disclose a computer aided diagnostic system comprising: a first sick portion detecting device (700) configured to detect a sick portion candidate based upon an image acquired by one modality (column 10, lines 3-41); and an image transforming device configured to transform the image acquired by the modality (column 14, lines 6-25, referring to the MR data being segmented in such a way that it becomes suitable for visual and/or computerized comparison with images obtained from other modalities, and also the gray values being transformed so that they map to similar gray value regions and project the 3D image to the plane of mammograms). Further, Gilhuijs et al. disclose that their system includes a correspondence displaying device (702) that is capable of being configured to meet the functional limitations disclosed in instant claims 10-11 (column 14, lines 6-34). See Figure 2. However, they do not disclose a second sick portion detecting device configured to detect a sick portion candidate based upon the transformed image; and a detection result synthesizing device configured to compare the results of detection by the first and second sick portion detecting devices. As discussed previously, Wang et al. disclose that their invention includes creating a bimodal medical image (400) formed by the superposition of the medical images 200 and 300 (i.e. the results of the detection in the first and second medical images can be compared) (column 8, lines 44-55). Further, a suspect region 402 can be identified on the superimposed image (column 8,

lines 52-55). See Figures 2-4. At the time of the invention, it would have been obvious to one of ordinary skill in the art to include in the invention of Gilhuijs et al. a second sick portion detecting device configured to detect a sick portion candidate based upon the transformed image and a detection result synthesizing device configured to compare the results of detection by the first and second sick portion detecting devices. The motivation for doing so would have been that some features that may not be evident in either medical image may become apparent when the images are superimposed, as taught by Wang et al. (column 8, lines 52-55).

With regards to claims 16-18 and 28, Gilhuijs et al. disclose a computer aided diagnostic system and method, comprising: a first sick portion detecting device configured to detect a sick portion candidate based upon an image acquired by a modality which can sense plural tomographic images (column 9, line 51-column 10, line 41; column 11, lines 60-67, referring to obtaining 3D data) and an image reconfiguring device configured to reconfigure an image based upon stereoscopic image data acquired by the modality (column 11, lines 60-67, referring to using 3D data). Further, Gilhuijs et al. disclose that their system includes a correspondence displaying device (702) that is capable of being configured to meet the functional limitations disclosed in instant claims 17-18 (column 14, lines 6-34). See Figure 2. However, they do not disclose a second sick portion detecting device configured to detect a sick portion candidate based upon the reconfigured image; and a detection result synthesizing device configured to compare the results of detection by the first and second sick portion detecting devices. As discussed previously, Wang et al. disclose that their

invention includes creating a bimodal medical image (400) formed by the superposition of the medical images 200 and 300 (i.e. the results of the detection in the first and second medical images can be compared) (column 8, lines 44-55). Further, a suspect region 402 can be identified on the superimposed image (column 8, lines 52-55). See Figures 2-4. At the time of the invention, it would have been obvious to one of ordinary skill in the art to include in the invention of Gilhuijs et al. a second sick portion detecting device and a detection result synthesizing device. The motivation for doing so would have been that some features that may not be evident in a medical image may become apparent when the image is reconfigured, as taught by Wang et al. (column 8, lines 52-55).

7. Claims 5 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilhuijs et al..

As discussed above, Gilhuijs et al. meet the limitations of claims 1 and 7. Further, Gilhuijs et al. disclose that an image acquired by the second modality (or image generated by the image transforming device) is a simple X-ray radioscopic image (column 14, lines 6-9, lines 22-25). However, they do not specifically disclose that an image acquired by either of the first or second modality is an X-ray CT image. Gilhuijs et al. do disclose that their system can be applied to characterization of abnormal anatomic regions in other projection medical images, such as chest radiographs, and/or in volume medical, such as tomographic scans (i.e. CT scans) as would be readily apparent to those skilled in the art (column 16, lines 1-10). At the time of the invention, it would have been obvious to one of ordinary skill in the art that an image acquired by

the first modality be an X-ray CT image, as Gilhuijs et al. disclose that their system can be applied using tomographic scans (column 16, lines 1-10).

8. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gilhuijs et al. in view of Nabatame (US Patent No. 5,740,225).

As discussed above, Gilhuijs et al. meet the limitations of claim 14. Although they do not specifically disclose that the modality is X-ray CT and an image analyzed by the sick portion detecting device is plural axial images reconfigured by the X-ray CT, they do disclose that their system can be applied to characterization of abnormal anatomic regions in other projection medical images, such as chest radiographs, and/or in volume medical, such as tomographic scans (i.e. CT scans) as would be readily apparent to those skilled in the art (column 16, lines 1-10). At the time of the invention, it would have been obvious to one of ordinary skill in the art that an image acquired by the first modality be an X-ray CT image, as Gilhuijs et al. disclose that their system can be applied using tomographic scans (column 16, lines 1-10). However, Gilhuijs et al. do not specifically disclose that the image reconfiguring device generates a digitally reconstructed radiograph based upon the plural axial images.

Nabatame discloses a radiation therapy planning method which accurately determines an isocenter and a radiation field with theuse of a digitally reconstructed radiograph (DRR) or translucent image; a system, and its apparatus (column 1, lines 8-12). They further disclose that their system involves acquiring a succession of axial images using a X-ray CT unit and includes a DDR developing unit for developing DRR of the subject viewed from a predetermined direction of radiation (column 5, lines 12-

56). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have the image reconfiguring device of Gilhuijs et al. generate a digitally reconstructed radiograph based upon the plural axial images. The motivation for doing so would have been to be able to use the DDR in radiation therapy planning, as taught by Nabatome (column 1, lines 7-12).

9. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gilhuijs et al. in view of Truwit et al. (US Patent No. 6,195,577).

As discussed above, Gilhuijs et al. meet the limitations of claim 14. Although they do not specifically disclose that the modality is X-ray CT and an image analyzed by the sick portion detecting device is plural axial images reconfigured by the X-ray CT, they do disclose that their system can be applied to characterization of abnormal anatomic regions in other projection medical images, such as chest radiographs, and/or in volume medical, such as tomographic scans (i.e. CT scans) as would be readily apparent to those skilled in the art (column 16, lines 1-10). At the time of the invention, it would have been obvious to one of ordinary skill in the art that an image acquired by the first modality be an X-ray CT image, as Gilhuijs et al. disclose that their system can be applied using tomographic scans (column 16, lines 1-10). However, Gilhuijs et al. do not specifically disclose that the image reconfiguring device generates a multiplanar reconstruction (MPR) based upon the plural axial images.

Truwit et al. disclose a system for positioning an interventional device in a body using a medical imaging system (column 1, lines 9-11). Further, they disclose that a multiplanar reconstruction of already obtained data can be obtained in order to verify a

target (column 3, lines 18-24). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have the image reconfiguring device of Gilhuijs et al. generate a multiplanar reconstruction (MPR) based upon the plural axial images. The motivation for doing so would have been to be able to verify a lesion/target, as taught by Truwit et al. (column 3, lines 21-24).

***Conclusion***

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine L. Fernandez whose telephone number is (571)272-1957. The examiner can normally be reached on 8:30-5, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni M. Mantis-Mercader can be reached on (571)272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ELENI MANTIS MERCADER
SPE 3768